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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,945	11/13/2001	Juan Mantelle	041457-0633	6420

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EXAMINER	
EBRAHIM, NABILA G	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/986,945	MANTELLE ET AL.	
	Examin r	Art Unit	
	Nabila G. Ebrahim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/14/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt of Information Disclosure Statement filed on 3/14/06 is acknowledge.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/14/06 has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "at least one of which is of low molecular weight drug" the word "low" renders the claim indefinite since there is not a specific definition given to the value or the range of "low molecular weight" in the art. It is not clear in the claim how low is the molecular weight of the drug and if it is very "low" or moderately "low" or at the upper border of the "low" molecular weights.

a) Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention. The claim recites "below processing temperatures" the phrase renders the claim unclear because this processing temperature is not recited. Explanation is needed.

b) Claim 1, 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "equal to or greater than the normal boiling points of the at least one low molecular weight drug". The meaning is vague since the drug is not known; there is no way to compare its boiling point.

Claim Objection

Claim 6 is objected to because of the following informalities: The claim recites, "arrange of 1 to 40 weight per cent". Deletion of the space in the word "percent" is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, and 10-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Miranda Jesus et al. WO 9300058 (Miranda).

Miranda teaches transdermal drug delivery system and more particularly,

to a transdermal drug delivery composition wherein a blend of polymers is utilized to affect the rate of drug delivery from the composition. The composition comprises a blend of polymers, and a therapeutically effective amount of a drug or more, which amount may reach between 5-40% by weight; this percentage is within the percentage recited in claim 6 (page 2). In a preferred embodiment of the improved pressure-sensitive adhesive, the first polymeric adhesive material is a polyacrylate and the second adhesive material is a polysiloxane (page 6). The shear resistant of the acrylic polymer in a preferred embodiment of the invention, the multiple polymer adhesive system comprises a blend of an acrylic shear-resistant pressure-sensitive adhesive and a silicone pressure-sensitive adhesive (page 5). Miranda discloses that the transdermal drug delivery device may include a backing material and a release liner as is known in the art (page 3). The drug comprised in the transdermal system may be nicotine (page 7), and the pressure-sensitive adhesive composition of the type, which is suitable as a matrix for controlled release of a bioactive agent (page 5). Miranda also suggests a free base, free acid drug (claim 34). Instant claim 4 recites a shear resistance that reaches 100 hours, however, Miranda teaches the shear resistance of 99 hours which is almost the same value and also teaches that polyacrylate is preferably present in the pressure-sensitive adhesive composition in an amount ranging from about 2-96% by weight and the polysiloxane is present in an amount ranging from about 98-4%, and the composition according to Miranda comprises fillers, and excipients (page 6). The same steps of instant claim 17 are recited in (example 1) of Miranda who added the nitroglycerin was added as a solution in

toluene mixed together with the polyacrylate. The resulting composition had the ingredient concentrations on a "dry" basis, that is, after removal of volatile process solvents.

Conclusion: claims 1-6, and 10-21 are anticipated by Miranda.

3. Claims 1-5, 7, 8, 10, 12, 14-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Pfister et al EP0524776

Pfister teaches a silicone pressure sensitive adhesive composition, which is compatible with drugs, excipients, co-solvents and skin penetration enhancers is disclosed which includes a cohesive strengthening agent. The adhesive is useful as a transdermal drug delivery device. A blend of polymers are used in the invention like siloxane polymers (page 3, line 10+), and acrylic acid polymers of high shear resistance that has molecular weights from about 1,000,000 to about 4,000,000 (page 5, lines 13+), nicotine-based drug, and co-solvent excipients (page 2, lines 13+). Note that instant claim 7 recite a molecular weight of about 600,000 to about 1,000,000. Shear values were measured by using a 4.5 lb. rubber roller and allowed to equilibrate for 20 minutes. The specimen is mounted into the jaws of the Instron and pulled at a speed of 0.5 cm/min. and the peak load required to shear and separate the laminate is recorded in kg (page 8, lines 14+, see also table C2), It is the position of the Examiner that since the ranges of the molecular weight of the acrylic polymers overlap at the 1,000,000 value then it is expected that the shear resistance values should be overlapping. With regard to instant claim 5, Pfister discloses that the liquids are allowed to evaporate in room temperature (see examples A and B), which makes the

composition substantially free of water and solvents. Pfister also discloses a pressure sensitive adhesive sandwiched between a backing substrate and a release liner (figure 1), and the delivery device is a matrix-type for a bioactive agent or drug in place within a transdermal patch (see figure 2) having the sufficient tack and shear to remain in place under conditions of use. Tack, peel, and adhesion values are disclosed (page 7, lines 40+). The methods recited in instant claims 17, and 21 is a conventional method comprising mixing polymer(s), drug(s) and solvent(s), forming a matrix then evaporating the solvent. The method is disclosed in example A, and B.

Conclusion: Claims 1-5, 7, 8, 10, 12, 14-21 are anticipated by Pfister.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of

35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfister et al. EP 0524776 in view of Lee et al US 5284660.

Pfister has been discussed above. Pfister did not disclose the percentage of the drug used.

Lee teaches a device suitable for transdermal administration has a backing layer, which is not permeable to the agent to be delivered (col. 4, lines 10+). The delivered drug can be nicotine (col. 7, line 23); the amount of the drug is 40% of the dry composition (example 1, claims 13, 14, 19, and 20). In addition, it is the position of the Examiner to call the attention of the Applicant that adjusting a specific transdermal dose of a drug is within a skilled artisan according to the condition it will be used for among many other factors while choosing between the different kinds of polymers recognized in the art to build a release-profile is also within the skills of an artisan unless documented by unexpected data results.

Accordingly, it would have been obvious to one skilled in the art at the time the invention was made to combine the knowledge of Pfister with the dosage disclosed by Lee, the motive would be the disclosure of pfister that his invention provide a transdermal pressure sensitive with having the sufficient tack and shear to remain in place under conditions of use.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim 5/26/06

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER